

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P-0043]

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**Determination That Piperacillin for Injection USP, 40-Gram Pharmacy Bulk Package,
Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that piperacillin for injection USP (PIPRACIL), 40-gram (g) pharmacy bulk package, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for piperacillin for injection USP, 40-g pharmacy bulk package.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

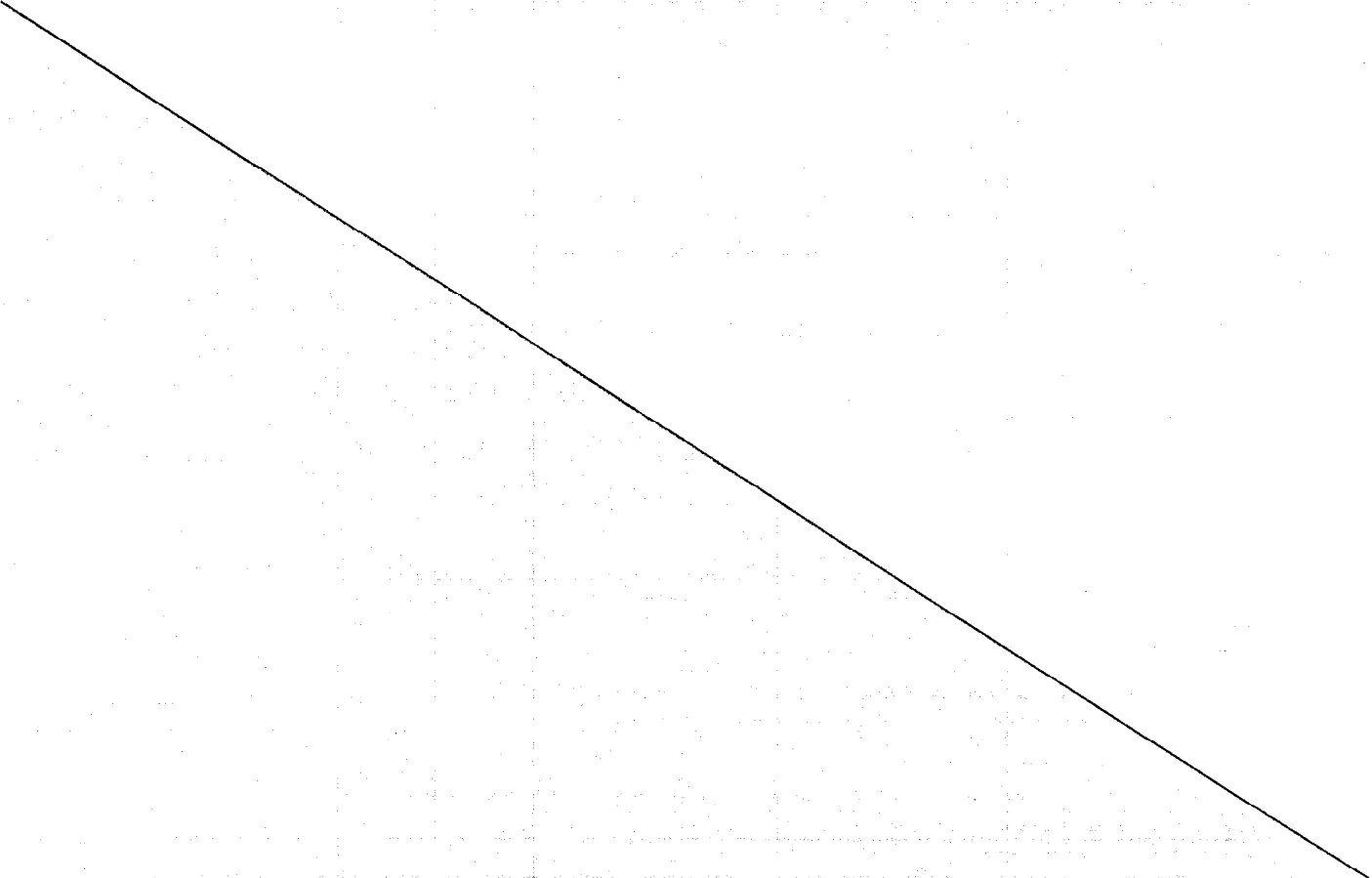
Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Piperacillin for injection USP, 40-g pharmacy bulk package, is the subject of approved NDA 50-545 held by Lederle (part of Wyeth-Ayerst Pharmaceuticals) under the trade name PIPRACIL. Piperacillin for injection USP, 40-g pharmacy bulk package, is a broad-spectrum penicillin indicated for the treatment of serious infections and for prophylactic use in surgery. According to information from Wyeth-Ayerst submitted in 2001, production of the 40-g pharmacy bulk package was discontinued. On January 17, 2002, Mr. Michael Lisjak submitted a citizen petition (Docket No. 02P-0043) under 21 CFR 10.30 and 314.122, requesting that the agency determine whether piperacillin for injection USP, 40-g pharmacy bulk package, was withdrawn from sale for reasons of safety or effectiveness. The petitioner seeks this determination in preparation for filing an ANDA for piperacillin for injection USP, 40-g pharmacy bulk package.

The agency has determined that Wyeth-Ayerst's piperacillin for injection USP, 40-g pharmacy bulk package, was not withdrawn from sale for reasons of safety or effectiveness. Two grounds support the agency's finding. First, Wyeth-Ayerst continues to market PIPRACIL in 2-, 3-, and 4-g vials. The 40-g pharmacy bulk package is a larger package of the same product; it contains up to 20 doses of piperacillin for injection USP. Second, the petitioner identified no data or other

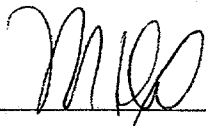
information suggesting that PIPRACIL (piperacillin for injection USP, 40-g pharmacy bulk package) was withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports, but has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, Wyeth-Ayerst's piperacillin for injection USP, 40-g pharmacy bulk package, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list piperacillin for injection USP, 40-g pharmacy bulk package, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing



for reasons other than safety or effectiveness. ANDAs that refer to piperacillin for injection USP, 40-g pharmacy bulk package, may be approved by the agency.

Dated: 6/24/02
June 24, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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